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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/978,634	11/25/1997	ELAZAR RABBANI	ENZ-53(DIV-2	4640
28170	7590	10/21/2005	EXAMINER	
ENZO DIAGNOSTICS, INC. C/O ENZO BIOCHEM INC. 527 MADISON AVENUE 9TH FLOOR NEW YORK, NY 10022			SCHULTZ, JAMES	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/978,634

Applicant(s)

RABBANI ET AL.

Examiner

J. D. Schultz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 245-283 is/are pending in the application.
- 4a) Of the above claim(s) 245-274 and 277-282 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 275, 276, 283 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 27 Oct. 2003.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Status of Application/Amendment/Claims***

Applicant's response filed 30 June 2005 has been considered. Rejections and/or objections not reiterated from the previous non-final office action mailed 25 March 2003 are hereby withdrawn. Applicants responses dated 29 September 2003 and 2 June 2004 are acknowledged. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application. Applicants request for reconsideration dated 29 September 2003 is responded to herein; however, the claim set accompanying said request was not in compliance with 37 CFR 1.121. The claims submitted 2 June 2004 corrected this oversight, and is the claim set currently under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants sequence submission entered 29 September 2004 and subsequent amendment to the specification to add missing SEQ ID NOS: puts the instant application in apparent compliance with 37 CFR 1.821-1.825.

***Election/Restrictions***

Claims 245-274, and 277-282 are withdrawn from consideration as being directed to non-elected species.

In applicants response dated 6 January 2003 to the requirement for election of species mailed 3 December 2002, applicants elected, among other things, the species drawn to monomeric units which are attached to a binding matrix comprising a polymer

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through noncovalent polymeric interactions between said polymer of said monomeric unit and said polymer said binding matrix.

Applicants' most recent response of 30 June 2005 canceled the elected subject matter recited above in claim 245, which is the independent claim of the claim set of 245-274, and 277-282. However, claim 275 was amended to reintroduce the elected subject matter. Accordingly, since the elected subject matter appears only in claim 275 and dependent claim 276 and 283, only claims 275, 276, and 283 are examined herein. Although claims 277-282 also depend from claim 275, claims 277-282 are drawn exclusively to nonelected subject matter resulting from the restriction requirement discussed above.

Accordingly, claims 245-274, and 277-282 are withdrawn from consideration as being directed to non-elected species. See 37 CFR 1.142(b) and MPEP § 821.03.

It is noted that although claim 245 has been withdrawn, and is therefore not the subject of the present examination, the cancellation of subject matter therein includes the final period of claim 245, and would therefore be objected to if said claim were to be examined.

***Response to Arguments, Claim Rejections - 35 USC § 112***

Claims 275, 276, and 283, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application

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was filed, had possession of the claimed invention, and is repeated for the same reasons of record as set forth in the action mailed 25 March 2003.

The instant rejection was set forth on the grounds that the breadth of the terms used in the claims is so broad that one of skill in the art would not be able to envision a representative number of structures that fall within the broad genus as claimed. Before answering applicants arguments, is considered important to first reiterate the breadth of the claim language and discuss the breadth of certain terms and their meanings as defined in the specification and the prior art.

Claim 275 is drawn to "a multimeric composition comprising more than one monomeric unit, said monomeric unit comprising a compound and polymer and wherein said monomeric units are attached to a binding matrix comprising a polymer through noncovalent polymeric interactions selected from the group consisting of hydrogen bonding and dipole interactions and combinations thereof, between said polymer of said monomeric unit and said polymer of said binding matrix."

As suggested above, the basic terms of claim 275 are considered to be so broad as to render one of skill in the art reading such a claim and attempting to envision the claimed invention unable to do so.

The specification discloses that a monomeric unit comprises a compound and a polymer. The specification does not define these broad terms, but merely lists what may be embraced by their recitation. Furthermore, the terms used to define these broad terms are themselves very broad. For example, the specification teaches that the compound may be a naturally occurring compound, a modified natural compound, a synthetic compound, or a recombinantly produced compound, or a combination of such

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compounds. More specifically, the compound can comprise a protein, monosaccharide, oligosaccharide, polysaccharide, fatty acid, fatty acid ester, or a polynucleotide, a hormone, a polyclonal or monoclonal antibody, f(ab) fragment, a growth factor, a lymphokine, a cytokine, a cellular matrix protein, a ligand, vector, bacterium, or virus, or a combination of these. This list refers only to the compound of the monomeric unit, although certain examples from a list of compounds would certainly also fall within the definition provided for a polymer, such as proteins, nucleic acids, antibodies, cytokines, lymphokines, etc. Virtually any biological molecule fall is considered to fall under such scope.

Thus, one of skill seeking guidance from the specification in clearly defining these broad terms would therefore include the art recognized definitions present in the prior art. A review of CancerWeb's online medical dictionary definition (<http://cancerweb.ncl.ac.uk>) of the term "monomer" results in the following definition: "a single molecule that is the subunit of a polymer". A polymer in turn, is defined as "a macromolecule made of repeating (monomer) units or protomers". A compound, according to CancerWeb's definition, is "a material made up of two or more elements". Thus, the basic terms of claim 275 are considered to be so broad as to render one of skill in the art reading such a claim and attempting to envision a representative sample of compounds that characterize the extent of a genus of such breadth unable to do so.

In response, applicants assert that a representative number of species have been provided. Applicants point to specific examples and provide a table at page 11 which lists references to molecules embraced by the claimed scope. However, the submission is not considered convincing, because all such examples define only a very narrow set of

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compositions that fall under the claimed scope. A selection of examples from the table is provided below, followed by the examiner's reasons why such entries are not considered to provide reasonable support for the claimed breadth.

For example, applicants argue that support can be found from the following statement: "[p]referred the polynucleotide segment attached to the compound does not bind to itself or hybridize together or is self-complementary." This statement merely suggests that one quality of one potential polymer (a polynucleotide) out of many possible polymers might be excluded.

Another allegation of support is pointed to in the following statement: "polymers attached to compounds may be selected from the same group of polymers as those comprising matrices as long as they bind noncovalently". This phrase does not further define the claimed invention, but rather simply states what could be included in the genus.

Another phrase which is alleged to provide support: "when bonding is through hydrogen bonding or complementarity, if the monomer unit has a polynucleotide sequence attached, the corresponding binding matrix should have the complementary nucleic acid sequence". This statement merely suggests that if the polymer comprises one of the many possible polymers (a polynucleotide in this case), and if it is hydrogen-bound to another polynucleotide from among the many possible polymers, that they should be complementary. This is elemental. If polynucleotides are hydrogen-bound to each other, they by default must have some degree of complementarity. Is maintained at the remainder of the entries in the table also lack the blaze marks that one of skill would look for in attempting envision the instant invention

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It is granted that there is some discussion and apparent contemplation that the polymer may be a polynucleotide. However, as stated in the specification, the polymer can also comprise a protein, antibody, cytokine, or lymphokine, etc. without limit.

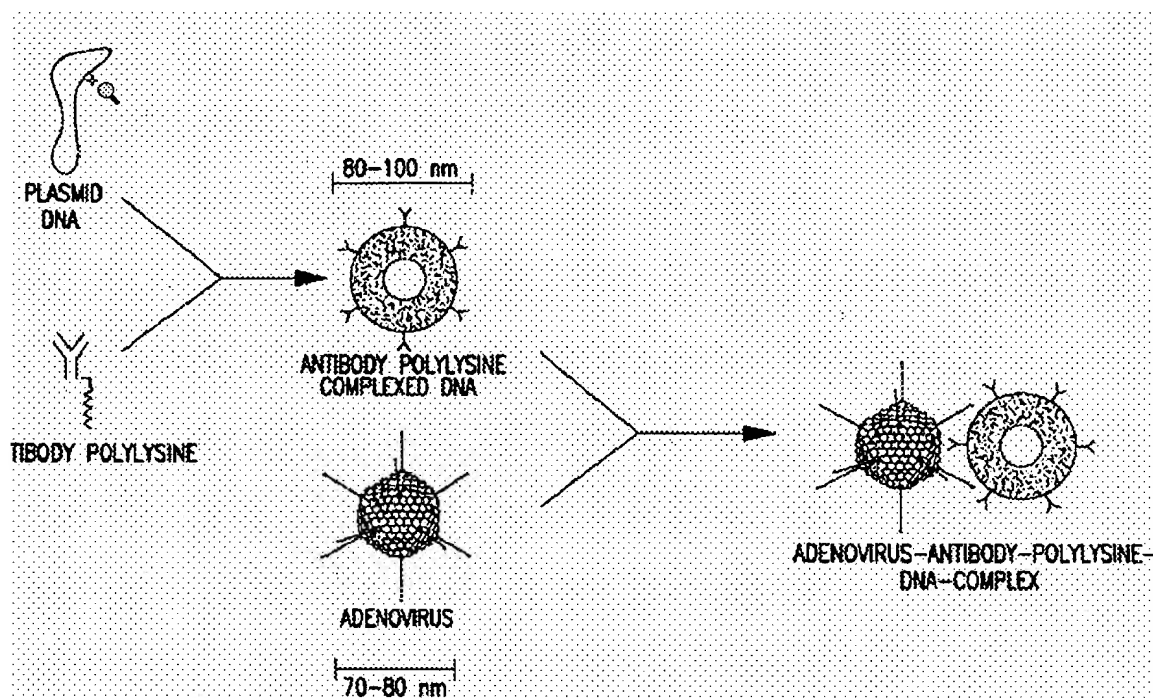
Furthermore, the recitation of compound is even more broad, whereby the compound may be a protein, monosaccharide, oligosaccharide, polysaccharide, fatty acid, fatty acid ester, a hormone, a polyclonal or monoclonal antibody, f(ab) fragment, a growth factor, a lymphokine, a cytokine, a cellular matrix protein, a ligand, vector, bacterium, or virus, or a combination of these. In the face of such breadth, is maintained that one of skill attempting to envision a representative sample of the genus of broadly claimed molecules would be unable to do so based upon the teachings of the instant specification and those of the prior art.

***Response to Arguments, Claim Rejections - 35 USC § 102***

Claims 275, 276, and 283 are rejected under 35 U.S.C. 102(e) as being anticipated by Curiel et al. (U. S. Patent Number 5,521,291). This rejection is similar to that already of record, but is modified to address applicants newly introduced claim limitations.

Applicants argue that Curiel et al. cannot anticipate claim 275 because Curiel does not contain all the elements of the claimed invention when considering the new limitations wherein the monomeric units of the multimeric complex are attached to a binding matrix by hydrogen bonding or dipole interactions or combinations thereof. Figure 1 of Curiel teaches a monoclonal antibody linked to a polylysine which is complexed with plasmid DNA, wherein the polylysine antibody complex DNA is then exposed to an adenovirus that is recognized by the antibody:





Applicants argue that if the adenovirus were the binding matrix and antibody/polylysine complex were the monomeric unit, that the polylysine moiety would not be bound to the adenovirus via either hydrogen bonds or dipole dipole interactions, and that therefore Curiel cannot anticipate. This is agreed. Applicants also argue that a second interpretation of Curiel set forth by the examiner could also not anticipate the instant claims, whereby the monomeric unit is the adenovirus and the antibody/polylysine complex is the binding matrix, because the monomeric unit would not comprise a polymer and a compound. This is not adopted, however, because the breadth of the term "polymer" and "compound" is such that the adenovirus could comprise a monomeric unit; an adenovirus comprises proteins which are polymers, as well as numerous compounds, such as nucleotides.

Furthermore, this is not the only interpretation of Curiel that would anticipate the instant invention. For example if the monomeric unit comprising the compound and polymer were considered to be the antibody/polylysine complex of Curiel, wherein the

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antibody is the compound and the polylysine is the polymer, the plasmid DNA could therefore be the binding matrix, in which case the polylysine (i.e. the polymer) associates with plasmid DNA (i.e. the polymer of the matrix) via a combination of dipole interactions and hydrogen bonding. By this interpretation, the compound comprises a protein (consistent with claim 276 of the instant specification), whereas the polymer is polylysine (consistent with page 74 of the instant specification), and the matrix is a polynucleotide (consistent with page 73 of the instant specification). Finally given this interpretation more than one compound is attached to the polymer, as specified in claim 283. Accordingly, Curiel, by this interpretation, is considered to anticipate the instant invention.

### *New Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 275, 276, and 283 are rejected under 35 U.S.C. 102(b) as being anticipated by Leibold et al. (Proc. Natl. Acad. Sci 1988, 85:2171-2175).

The invention of the above claims is drawn to a multimeric composition comprising more than one monomeric unit, said monomeric unit comprising a compound, which may be a protein, and a polymer and wherein said monomeric units are attached to a binding matrix comprising a polymer through noncovalent polymeric interactions selected from the group consisting of hydrogen bonding and dipole interactions and

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combinations thereof, between said polymer of said monomeric unit and said polymer of said binding matrix. Claim 283 is drawn to the composition of claim 275, wherein more than one compound is attached to a polymer.

Leibold et al. teaches a gel shift assay, wherein proteins (i.e. a compound) cross-linked to polynucleotides (i.e. a polymer) are run through a gel (i.e. a binding matrix comprising a polymer). One of ordinary skill would understand that the polynucleotide/protein monomer is bound to the gel non-covalently, through a complex combination of interactions that is considered to include both hydrogen bonding and dipole interactions. This is particularly true in view of the broad claim recitation that the binding be through “dipole interactions”. Interpreted broadly, “dipole interactions” can involve any two molecules that interact, since every molecule has a dielectric constant which gives rise to said dipole. Thus any molecules that interact, as the monomer and gel of Leibold clearly do, involves interactions of their dipole moments (i.e. their dielectric constants). Therefore, Leibold et al. is considered to teach all the limitations of the claims above.

### ***New Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 283 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in

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the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Claimed 283 is drawn to the composition of claim 275, "wherein more than one compound is attached to a polymer". While there are two polymers recited in claim 275, claim 283 is interpreted as claiming "more than one compound" attached to either of such polymers, and is therefore not considered indefinite. However, Applicants have failed to indicate where support exists for more than one compound attached to any polymer of claim 275. Applicants merely indicated that "the new claims are supported by the specification", and that "[n]o new matter has been added."

Furthermore, after a review of the specification as filed, it is not apparent where adequate support exists in regards to this limitation. There does not appear to be any contemplation of how many compounds are attached to either polymer, and in particular, no reference to a requirement that the number of compounds be more than one, regardless of which polymer they are attached to. Should applicants disagree, applicants are invited to point out with particularity by page and line number where specific support exists for more than one compound attached to either polymer of claim 275 as now recited.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

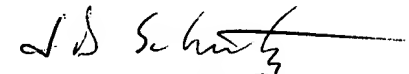
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JDS

  
**J.D. SCHULTZ, Ph.D.**  
**PATENT EXAMINER**